

CLAIMS

We claim:

1. A process of preparing a controlled release oral dosage form comprising:
 - (a) mixing an active pharmaceutical ingredient and an acrylic polymer to yield a mixture;
 - (b) forming said mixture into a solid unit dosage form, and
 - (c) curing said solid unit dosage form.
2. The process of claim 1, wherein the active pharmaceutical ingredient is selected from the group consisting of morphine, hydromorphone, codeine, oxymorphone, nalbuphine, hydrocodone, dihydrocodeine, dihydromorphone, buprenorphine, oxycodone, naltrexone, naloxone, and pharmaceutically acceptable salts thereof.
3. The process of claim 1, wherein the acrylic polymer is ammonio methacrylate copolymer.
4. The process of claim 1, wherein the acrylic polymer comprises of about 10% to about 90% of the weight of said mixture.
5. The process of claim 4, wherein the acrylic polymer comprises of about 30% to about 70% of the dry weight of said mixture.
6. The process of claim 1 wherein the step of forming said mixture into a solid unit dosage form comprises dry granulating said active pharmaceutical ingredient with said acrylic polymer.
7. The process of claim 1 wherein the step of forming said solid unit dosage form comprises compressing said mixture.
8. The process of claim 1 wherein said solid unit dosage form is a tablet.
9. A process of preparing a controlled release oral dosage form comprising:
 - (a) mixing oxycodone and ammonio methacrylate copolymer to yield a mixture;
 - (b) forming said mixture into a tablet using dry granulation or direct compression; and
 - (c) curing said tablet for a time and at a temperature sufficient such that a DSC scan will produce no significant peaks in the region of from about 40°C to about 70°C.
10. A controlled release oral dosage form produced according to the process comprising:
 - (a) dry mixing an active pharmaceutical ingredient and an acrylic polymer to yield a mixture;
 - (b) forming said mixture into a solid unit dosage form; and
 - (c) curing said solid unit dosage form.
11. A controlled release oral dosage form produced according to the process comprising:
 - (a) dry mixing oxycodone hydrochloride and ammonio methacrylate copolymer to yield a mixture;

- (b) forming said mixture into a tablet using dry granulation or direct compression; and
(c) curing said tablet at a temperature between about 40°C and about 70°C.

12. A controlled release oral dosage form comprising an active ingredient dispersed in a sustained release matrix comprising an acrylic polymer, wherein said dosage form has been cured.
13. The controlled release oral dosage form of claim 12, comprising an acrylic polymer that exhibits no significant peaks in the region of from about 40°C to about 70°C on a DSC scan.
14. The controlled release oral dosage form of claim 12, wherein said acrylic polymer exhibits no significant peaks in the region of from about 46°C to about 64°C on a DSC scan.
15. A controlled release oral dosage form comprising an active pharmaceutical ingredient and a substantially uniform matrix which comprises from about 30% to about 70% of a cured ammonio methacrylate copolymer.